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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,105	07/08/2003	Isao Yamazaki	KAS-187	7653
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,105

Applicant(s)

YAMAZAKI ET AL.

Examiner

NEIL TURK

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on October 14th, 2009. Claims 13-20 are pending. Claims 19 and 20 have been newly added. Claims 1-12 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation in claims 16-18 which recites, "...wherein each of said plurality of containers stores both of said first reagent and said second reagent in a package..." constitutes new matter in the claims. From Applicant's specification, the package is not a positive element of the device. Applicant's pre-grant publication (US 2004/0105783) in paragraph [0017] recites that the reagent containers *may be constructed such that* it can store in a single package both of a first reagent and a second reagent. This disclosure is related to the configuration of the reagent

container and its holding capabilities, and does not provide basis for the packages being positive elements of the device, as currently claimed in claims 16-18.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation to the reagent containers storing the first and second reagents in a package is unclearly recited. From Applicant's specification, it appears that the package is not a positive element of the device. Applicant's pre-grant publication (US 2004/0105783) in paragraph [0017] recites that the reagent containers may be constructed such that it can store in a single package both of a first reagent and a second reagent. This disclosure is related to the configuration of the reagent container. Applicant should amend the claims to recite that the reagent containers are constructed to allow a package to be contained therein which has both the first and second reagent. As such, prior art which discloses reagent containers that are capable of holding a package with first and second reagent will be said to read on the limitations of claims 16-18.

Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how first and second reagent is taken from the packages as necessary for the operation of the dispensing probes and thereby

the analysis by the analyzer. What structure is provided for piercing or gaining access to the reagents that are packaged? Does Applicant intend to claim a piercing structure attached to the dispensing probes for accessing the reagents therein. Further, claims 16-18 are unclear in how each of the dispensing probes relates to the first and second reagents stored in each package. Claim 13 recites that a first reagent dispensing probe is arranged to dispense the first reagent and a second reagent dispensing probe is arranged to dispense a second reagent. Now that claims 16-18 provide both first and second reagents in a single package, it is unclear how the first and second dispensing probes may function to selectively suck the first or second reagent as recited.

Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 14, 16, 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as obvious over Ohishi et al. (6,019,945), hereafter Ohishi, in view of Ginsberg et al. (4,234,538), hereafter Ginsberg, and in view of Itoh (5,445,037)

Ohishi discloses a sample analysis system. Ohishi shows in figure 3 a controlled (connected to computer 6B and control unit 40; computer 6A as designated in fig. 2) analysis unit 3B in which there are a plurality of reagent disks 26a, 26b. Ohishi also shows a plurality of reagent dispensing probes 8a, 8b arranged to suck reagent from one of the reagent containers (12a, 12b; which are capable of holding first and second reagents in a package), and inject the reagent into one of the reaction cells 46b (within reactor section 5b). Examiner further asserts that the reagent dispensing probes 8A, 8B are controlled so that only one of the first and second reagent dispensing probes sucks/injects first or second reagent during a predetermined cycle of a pitch and a stop of said reaction disk. This is such that one of the plurality of reactor cells 46B, which has been preloaded with sample (analysis item), is brought to a stop at a first position at which reagent pipetter 8A is controlled to inject first reagent into reactor cell 46b, while the second dispensing probe is uncontrolled and does not dispense second reagent at

such a pitch and stop of the reactor cell. Ohishi discloses that the reactor cell is then moved to arrive at a second position where pipetter 8B is controlled to inject the second reagent to the reactor cell 46, while the first pipetter is idle (lines 23-67, col. 6; lines 1-13, col. 7, fig. 3). Ohishi discloses light source 14a and multi-wavelength photometer 15a for optical measurement of the reactor solution in reactor cells 46b; Ohishi further discloses that the signal from photometer 15a is converted by A/D converter 30A and distributed over computer 6A to host control computer 40 (lines 1-23, col. 6).

Ohishi does not disclose including first and second reagent dispensing probes arranged at each of the reagent disks (four probes; first, second, third, and fourth as in cl. 19&20). Ohishi also does not disclose that the controller controls the dispensing of the first reagent by the first reagent dispensing probe of the first reagent disk and by the first reagent dispensing probe of the second reagent disc to be performed in an alternating manner (equivocal to the first and third dispensing probes as in cl. 19, and further the second and fourth probes as in cl. 20).

Ginsberg discloses an automatic analyzer that includes first and second reagent dispensers 44, 46 arranged about a reagent disc 42, such that first and second reagent are added from the same reagent disk to a reaction cuvette 32 (analysis item; analyzed by light source 50/detector 52) (abstract; lines 20-32, col. 5, fig. 1).

Itoh discloses a sample dispensing apparatus. Itoh discloses that the apparatus includes a plurality of probes, each probe including a probe head 32 and 38 with nozzles 33, 39 for aspirating and discharging the sample. Itoh discloses that the plurality of nozzles being movable to aspirate and discharge sample independently of

each other (lines 33-67, col. 3+; fig. 1). Itoh further discloses that the take up/distributing unit 30 operations are performed alternately by the pair of taking up/distributing mechanisms 30A, 30B (which include the probes and nozzles for dispensing), the taking up/distributing time is shortened, thereby improving the processing speed of the apparatus (line 65, col. 9 – line 5, col. 10).

It would have been obvious to modify Ohishi to include first and second reagent dispensing probes arranged at a disk, and further to control the first and second reagent dispensing probes so that a single analysis item is analyzed by using reagents in reagent containers arranged on the same reagent disk such as taught by Ginsberg in order to increase throughput by providing a second and clean dispensing probe that is available for immediate use on the next progression, and further providing both necessary reagents on a single reagent disk as taught by Ginsberg as an alternative arrangement of the necessary first and second reagents, which provides a single reagent disk for carrying out the necessary reaction, so that throughput is not decreased by breakdown of the other reagent disk. Further, it would have been obvious to apply this to both reagent disks of Ohishi (26A and 26B; thereby yielding four reagent dispensers in total) so that a second, clean dispensing probe would be available to both of the first and second reagents contained at the reagent disks 26A, 26B; thereby throughput would increase as fewer cleaning steps for the dispensing probes would be required and more probes would be available to dispense reagent into the reaction containers within the reaction disk.

It would have further been obvious to modify Ohishi to have the controller control operations of the first reagent dispensing probe of the first reagent disk and the first reagent dispensing probe of the second reagent disk (and likewise with respect to the first and third probes, and second and fourth probes as in cls. 19&20) such as taught by Itoh who discloses that an alternating operation of the plurality of probes provides to yield faster processing time and thereby higher throughput.

Claims 15 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohishi in view of Ohishi in view of Ginsberg and in view of Itoh as applied to claims 13,14, 16, 17, 19, and 20 and in further view of Minekane (4,808,380).

Ohishi/Ginsberg/Itoh does not disclose at least one reagent disk arranged inside a reaction disk.

Minekane discloses an automatic chemical analyzing apparatus. Minekane discloses a cuvette rotor 18 in which cuvettes 20 are mounted in an annular array to receive sample and reagent to be then analyzed by a photometer (reaction disk 18 with reaction cells 20). Minekane further discloses reagent supply 14, which has a pair of coaxial reagent rings 24 and 26, and is placed peripherally within the ring of cuvette arrays (arranged inside the reaction disk) (lines 19-67, col. 2, fig. 1).

It would have been obvious to modify Ohishi /Ginsberg/Itoh to arrange reagent disks inside the reaction disk such as taught by Minekane in order to save space and optimize the workspace area.

Response to Arguments

Applicant's arguments filed October 14th, 2009 have been fully considered but they are not persuasive. With regards to claims 16-18 rejected under both 35 USC 112, 1st paragraph, and 35 USC 112, 2nd paragraph, Examiner argues that Applicant's amendments to the claims have not remedied the applied rejections. The claims are maintained rejected for the reasons discussed above.

Applicant's arguments with respect to claims 13-20 have been considered but are moot in view of the new ground(s) of rejection, as discussed above in the body of the Action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797